510(k) Summary

Submitted by:	Integra York PA, Inc. 589 Davies Drive York, PA 17402 USA
Contact Person:	Stephanie Sheesley Sr. Regulatory Affairs Manager Integra York PA, Inc. 589 Davies Drive, York, PA 17402 USA Phone: (717) 717-840-3522 Facsimile: (717) 840-9347
Date Prepared:	August 15, 2013
Device Trade Name:	Integra® Jarit® DeBakey Heparin Cannula, Integra® Jarit® Stoney Heparin Injector, and Integra® Jarit® Heparin Flushing Needle
Device Common Name:	Cardiovascular cannulas, injectors, and needles
Part Numbers:	310-379, 310-382, 310-383, 310-384
Classification Name:	Cannula, Catheter
Device Class:	Class II
Product Code:	DQR
CFR Classification:	21 CFR 870.1300

OCT 28 2013

Device Description:
Integra® Jarit® Heparin Cannulas, Injectors, and Needles are manual, stainless steel catheter cannulas provided in various sizes, shapes, and lengths for use during cardiovascular surgical procedures such as coronary artery bypass surgery. The cannulas are intended to be connected to a syringe filled with heparinized saline to confirm there is no leakage as well as ensure patency of harvested and/or grafted veins. The syringes are not being supplied with the cannulas nor are the syringes offered by Integra; therefore they are not part of this submission. These reusable devices are packaged non-sterile and are steam sterilizable.

Indications For Use:
Integra® Jarit® Heparin Cannulas, Injectors, and Needles are used in conjunction with various syringe sizes (not supplied by Integra®) for flushing, irrigation and solution injection into a vessel or cavity during vascular, bypass or other cardiovascular surgical procedures.

Predicate Devices:

510(k) #	Device	Manufacturer
Preamendment	DeBakey Heparin Cannula	Pilling Co.
Preamendment	Stoney Heparin Injector	Pilling Co.
Preamendment	Heparin Flushing Needle	V. Mueller
K030788	DeBakey Vessel Dilator	Geister Medizintechnik GmbH

There are no differences in technology, materials, intended use, or design between the subject devices and the above predicates.

Performance Standards:

No performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for these devices. However, the Integra® Jarit® Heparin Cannulas, Injectors, and Needles conform to the following standards:

- ANSI/AAMI ST79:2010 & A1:2010 Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ANSI/AAMI/ISO 14937:2009 Sterilization of health care products—General requirements for characterization of a sterilizing agent and the development, validation, and routine control of a sterilization process
- ASTM TIR 30:2003 A Compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- ASTM F 1089-02 Standard test method for corrosion of surgical instruments
- ISO 13402:1995 Surgical and dental hand instruments – Determination of resistance against autoclaving, corrosion and thermal exposure
- ISO 7153-1:2001 Surgical instruments- Metallic Materials- Part 1: Stainless Steel
- ASTM F899-11 Standard Specification for Wrought Stainless Steels for Surgical Instruments

Non-Clinical Tests Submitted:

Testing Performed	Results
Manual Cleaning Validation (Protein Analyses) per AAMI TIR30:2003.	**Pass**
Mechanical Cleaning Validation (Protein Analyses) per AAMI TIR30:2003.	**Pass**
Pre-Vacuum (wrapped) Steam Sterilization Validation per ANSI/AAMI ST79:2010 & A1:2010 and ANSI/AAMI/ISO 14937:2009 at 270°F (132°C) with an Exposure Time of 4 minutes and Drying Time of 30 minutes	**Pass**
Repeated Autoclave Testing, Boiling Water Testing, Copper Sulfate Corrosion Testing and Thermal Testing per ISO 13402:1995 and ASTM F 1089-02.	**Pass**
Mechanical Strength Testing – Laser Weld Joint	**Pass**
Mechanical Strength Testing – Brazed Joint	**Pass**

No biocompatibility testing was performed on the proposed devices as the 304 and 303 Stainless Steel Materials are recognized biocompatible materials per ASTM F899-11 and ISO 7153-1 and have a long history of safe and effective use as shown in the predicate devices.

Conclusions drawn from Non-Clinical Data:
All necessary testing has been performed on the Integra® Jarit® Heparin Cannulas, Injectors, and Needles and the results support the conclusion that the subject devices are substantially equivalent to the legally marketed predicate devices based on intended use, materials, technology, and design and as such, do not raise any concerns of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 28, 2013

Integra Lifesciences Corporation
c/o Stephanie Sheesley
Sr. Regulatory Affairs Manager
Integra York PA, Inc.
589 Davies Drive
York, PA 17402

Re: K131446
Trade/Device Name: Integra® Jarit® DeBakey Heparin Cannula, Integra® Jarit® Stoney Heparin Injector, and Integra® Jarit® Heparin Flushing Needle
Regulation Number: 21 CFR 870.1300
Regulation Name: Cannula Catheter
Regulatory Class: Class II
Product Code: DQR
Dated: August 28, 2013
Received: August 29, 2013

Dear Ms. Sheesley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K131466

Device Name: Integra® Jarit® Heparin Cannulas, Injectors, and Needles

Indications for Use:

Integra® Jarit® Heparin Cannulas, Injectors, and Needles are used in conjunction with various syringe sizes (not supplied by Integra®) for flushing, irrigation and solution injection into a vessel or cavity during vascular, bypass or other cardiovascular surgical procedures.

Prescription Use ✓ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter-Use (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)